

### REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 6-11, 14-19, 24,25, 39, 42, 43, 48, 50 and 67-76 have been cancelled without prejudice or disclaimer. Applicants reserve the right to file any unclaimed subject matter in one or more continuing applications. Claims 77-110 have been added. This amendment is fully supported by the originally-filed application and claims, specifically supported by original claims 7-10 and 49-50 and the specification on pages 2, 17 and 19. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. After amending the claims as set forth above, claims 77-110 are now pending in this application.

No new matter has been added. Support for claim 77 is found in original claim 49 with the N-terminal sequence added. Support for claim 78 is found as for claim 77, and in original claim 7. Support for claim 79 is found in original claim 8. Support for claim 80 is found in the specification at page 19, in the last sentence of the first paragraph thereof. Support for claim 81 is found in original claim 9. Support for claim 82 is found in original claim 10. Support for claims 83-84 is found in original claim 50. Support for claim 85 is found in the same manner as for claim 78 coupled with original claim 18. Support for claims 86-87 is found in the specification at page 2 in the first complete paragraph thereof and at page 17 in the middle of the first paragraph. Claims 88 and 89 correspond to previously presented claims claim 90 has support on page 12, at the beginning at line 13. Claims 91-94 correspond to original claims 41-43 and 50.

Support for claim 95 is provided by Example 3, page 34 and in the PEPTIDES section bridging pages 21 and 22. Claims 96-110 are supported in like manner as above, except that they are directed to the MANS peptide.

Accordingly, entry and consideration of claims 77-110 is respectfully requested.

Applicants acknowledge the withdrawal of the rejection of claims 1-4 and 6 based on obviousness grounds.

**1. The presently claimed invention is supported by the written description**

Claims 1, 6-11, 14-19, 24,25, 39, 42, 43, 48, 50 and 67-76 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement because the Examiner states that applicants were not in possession of the full scope of "active fragments" of a MARCKS protein. The previously rejected claims have been canceled and replaced by claims 77-110 which applicants submit more clearly define their invention. Claims 77-94 recite that the peptide consists of from about 10 to about 50 contiguous amino acids from the N-terminal sequence of SEQ ID NO: 3 (the MARCKS protein) and further recites that the peptide inhibits MARCKS protein-related mucus hypersecretion and claims 95-110 recite that the peptide is the MANS peptide and that it inhibits MARCKS protein-related mucus hypersecretion. The specification on page 12, beginning at line 8, discloses that a myristoylated peptide fragment of the N-terminal region of the MARCKS protein as well as other active peptide fragments are useful in methods of inhibiting mucus secretion. Applicants wish to point out that the pending claims do recite the structure of the peptide and have recited that a peptide with that structure (about 10 to about 50 contiguous amino acids from the N-terminal sequence of SEQ ID NO:3 or the MANS peptide) also functions to inhibit MARCKS protein-related mucus hypersecretion. Applicants submit that this claim language complies with the written description requirement, and that the specification describes the invention in sufficient detail that a person skilled in the art could conclude that the present inventors had possession of the claimed invention. The claimed methods utilize structurally defined peptides which possess specific functional activity. Although experimentation may be necessary to determine the amount of the peptides to administer to a cell, such experimentation is not undue, as the parameter of mucus inhibition can be measured by methods disclosed in the specification as in Examples 3 and 4, and by methods known to persons skilled in the art at the time of filing of the present application (see Eum *et al.*

enclosed with this response, as Exhibit 2 of Appendix A). Applicants submit that the specification does provide adequate written description in sufficient detail to one skilled in the art. Applicants respectfully request that the Examiner reconsider this rejection based upon the arguments presented herein and pending claims, and withdrawn this rejection.

**2. The presently claimed invention is enabled for the full scope of the claimed invention**

Claims 1, 6-11, 14-19, 24,25, 39, 42, 43, 48, 50 and 67-76 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled for the full scope of the claims. To support this rejection, the Examiner states that while she considers the specification enabling for inhibiting mucus secretion in a cell comprising the administration of the MARCKS derived peptide according to SEQ ID NO:1, she does not consider the specification enabling for any other peptide for inhibiting mucus secretion in cells. The Examiner further supports this rejection based upon the experimental data provided by the Martin declaration that she alleges only provides enablement for the administration of the MANS peptide. Based upon these statements by the Examiner, applicants respectfully submit that the Examiner should withdraw this rejection as applied to claims 95-110 that specifically recite using the MANS peptide to inhibit mucus secretion in cells. But in support of claims 77-94 that recite that the peptide used in the method consists of from about 10 to about 50 contiguous amino acids from the N-terminal sequence of SEQ ID NO: 3 (the MARCKS protein), applicants herewith provide a **declaration under 37 CFR § 1.132 of Dr. Indu Parikh** (Appendix A), a biochemist with extensive experience in protein/peptide chemistry. The data provided in Dr. Parikh's declaration shows that MANS peptide (BIO124) and other peptides of varying length from the N-terminus of the MARCKS protein, i.e., 1-10, 1-12, 1-16 and 1-20 amino acids, inhibit mucus secretion. This data supports the enablement of the method claims 77-94. It is respectfully requested that the Examiner consider Dr. Parikh's data in his declaration and withdraw the enable rejection of all of the claims, and particularly

withdraw this rejection with regard to claims 95-110 as the Examiner has previously indicated that method claims directed to the administration of the MANS peptide is enabled.

The Examiner has commented in regard to previous claim 19 (now for example recited in claims 86, 87, 102 and 103) that applicants have not set forth any correlation between treating a symptom associated with these diseases and actually treating the disease. Applicants' claims recite that the method inhibits mucus secretion in the subject and the subject can be afflicted with anyone of these diseases of which mucus hypersecretion is a symptom. Applicants submit that the present set of claims do not require a showing that a correlation exists between treating the symptom and treating the disease because treating a symptom of a disease is a method of treatment that will help the subject treated whether such treatment treats the disease or not.

### **3. Provisional Obvious-Type Double Patenting Rejection**

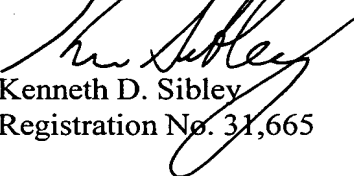
Claims 1, 6-11, 14-19, 24,25, 39, 42, 43, 48, 50 and 67-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 8-16, 20-27, 31-34, 37-42 and 47-51 of co-pending U.S. Serial No.: 10/180,753. Applicants traverse this rejection at this time as the claims of the co-pending have not yet been allowed and these claims may be amended which would obviate this provisional rejection. Applicants request that this rejection be held in abeyance until allowable subject in this application has been indicated by the Examiner.

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No fee is believed due, however the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account 50-0220.

It is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,



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Enclosure: Rule 132 Declaration of Dr. Parikh (Appendix A)

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